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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BEVIL J. HOGG, JEFFREY M. GARIBALDI, and
RAJU R. VISWANATHAN

Appeal 2010-001453
Application 10/674,914
Technology Center 3700

Before: STEVEN D.A. McCARTHY, KEN B. BARRETT, and
PHILLIP J. KAUFFMAN, Administrative Patent Judges.

KAUFFMAN, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 1-6, 8-17, 38-40, and 52.¹ We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

THE INVENTION

Appellants' claimed invention relates to "the use of electronic identifiers with automatically actuated flexible medical devices for controlling the distal end of an elongate medical device for efficient surgical navigation and target access." Spec. 1, para. [0002]. Claim 1, reproduced below, is illustrative of the claimed subject matter:

¹ Claim 51 is not before us on appeal as it was not rejected in the Office Action that is the subject of this appeal. See Office Action, dated December 10, 2008, pp. 1, 3 (cover page erroneously lists claim 51 as rejected; however the body makes clear that claim 51 is not rejected but is subject to an objection); see also App. Br. 2, 26 (stating that claim 51 should be treated as cancelled). The claims as set forth in the Appellants' Evidence Appendix appear to correspond to those on file as of January 9, 2008, the date of the last Amendment entered by the Examiner. The Appellants filed an Amendment on March 10, 2009. The Amendment stated that, "[i]n the event that the Office denies entry of Applicants' January 20, 2008 Supplemental Appeal Brief requesting reinstatement of the appeal, the Applicants respectfully request entry of this Response to the December 10, 2008 Office Action, which Response includes arguments presented in Applicants' Supplemental Appeal Brief." Amendment dated March 10, 2009 at 1. The record does not indicate whether the Examiner considered the March 10, 2009 Amendment. Even assuming that the Examiner did not consider the March 10, 2009 Amendment, the only change which the Amendment proposed to make to the claims was to cancel claim 51. Since the entry of the Amendment would not have changed the issues in this appeal, we will decide the appeal on the basis of the claims as set forth in the Appellants' Claims Appendix.

1. A medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end portion one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, and an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification;

a navigation device configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation;

an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and, spacing therebetween, that were obtained from the electronic identification device.

THE REJECTIONS

Appellants seek review of the following rejections:

1. Rejection of claims 1-6, 8, 9, 11-17, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis (WO 00/07641; published February 17, 2000) and Osadchy (US 6,266,551 B1; issued July 24, 2001).
2. Rejection of claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Osadchy, and Burnside (US 6,237,604 B1; issued May 29, 2001).
3. Rejection of claims 38-40 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Garibaldi (US 6,401,723 B1; June 11, 2002), and Osadchy.

CONTENTIONS AND ISSUES

Regarding the first rejection, Appellants argue claims 1-6, 8, 9, and 11-17 as a group. App. Br. 20. We select claim 1 as the representative claim, and claims 2-6, 8, 9, and 11-17 stand or fall with claim 1. See 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner found that Osadchy discloses an electronic identification device (digital microcircuit 90) on an elongate medical device (catheter 20) that includes information on the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements (coils 60, 62, 64) and the spacing between those elements (displacements d_y and d_z). Ans. 4, 8-9, 11.

Appellants present two arguments against the Examiner's rejection of claim 1. First, Appellants contend, "Osadchy's distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter," and does not take into account information on the

number of magnetically responsive elements and the spacing between those elements. App. Br. 14. For that reason, Appellants assert the proposed combination would not result in the subject matter of claim 1, and thus the Examiner has not articulated a sufficient reason for the proposed modification. App. Br. 14-15; Reply Br. 2-3. Second, Appellants contend that Osadchy teaches away from the proposed combination because a person having ordinary skill in the art would have modified Stereotaxis's system to include a calibration offset, based on the distance L, as taught by Osadchy, and in doing so would not have arrived at the subject matter of claim 1. App. Br. 15-16; Reply Br. 2-3.

The first issue is whether the proposed combined teachings of Stereotaxis and Osadchy would have rendered the subject matter of independent claim 1 obvious to a person having ordinary skill in the art.

Independent claim 38 calls for a memory device on a flexible medical device that includes information on the physical and geometric properties of that device, including one or more cross-sectional areas of the elongate device and an elastic property of the elongate medical device.

The Examiner found that Garibaldi teaches that the cross-sectional area of the coil wire of an analogous elongate medical device is directly proportional to the magnetic moment of the coil, which in turn is directly proportional to the magnetic torque applied to the distal end of the elongate medical device. Ans. 11 (citing Garibaldi, col. 4, ll. 36-42). The Examiner concluded that it would have been obvious to modify Stereotaxis's device "such that one or more cross-sectional areas of the elongate device are used in navigational control algorithms for guiding the device as taught by Garibaldi et al to effectively take into account the effect of the cross-sectional area on the magnetic torque of the elongate medical device." Id.

Appellants contend that Garibaldi discloses a teaching related to the cross-sectional area of a coil within a medical device, but does not disclose use of information regarding the cross-sectional area of the medical device for navigational control of the device. Reply Br. 5.

The second issue is whether the proposed combination of Stereotaxis, Osadchy, and Garibaldi would have led a person of ordinary skill in the art to the subject matter of independent claim 38.

ANALYSIS

Rejection of claims 1-6, 8, 9, 11-17, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis and Osadchy

Claims 1-6, 8, 9, 11-17

Appellants argument that Osadchy merely discloses an offset calibration based on the distance L does not address the Examiner's finding that Osadchy's coils 60, 62, 64 correspond to the claimed magnetically responsive elements, and that Osadchy's displacements d_y and d_z correspond to the spacing between those elements. See App. Br. 13-16; Reply Br. 2-3; Ans. 4. Because Appellants fail to address the rejection as articulated by the Examiner, we are unpersuaded by Appellants' assertion that the Examiner erred.

Further, even assuming, arguendo, Appellants are correct that a person of ordinary skill in the art would have modified Stereotaxis's system to include a calibration offset (based on the distance L) for the elongate medical device tip as taught by Osadchy, Appellants' argument does not convincingly explain how such a modification would have led a person of ordinary skill in the art in a direction divergent from modifying Stereotaxis's system so that the electronic identification device includes information on

the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements (coils 60, 62, 64) and the spacing between those elements (displacements d_y and d_z). See *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant.” (citation omitted)). In other words, assuming, *arguendo*, a person of ordinary skill in the art would have modified Stereotaxis’s system to include a calibration offset as taught by Osadchy, that does convincingly explain why a person of ordinary skill in the art would not have found it obvious to modify Stereotaxis’s system to include information on the physical and geometric properties of the elongate medical device as taught by Osadchy.

As such, we sustain the rejection of claim 1, and claims 2-6, 8, 9, and 11-17 fall with claim 1.

Claim 52

Independent claim 52, similarly to independent claim 1, calls for a memory device that includes information on the physical and geometric properties of the elongate medical device. The rejection of claim 52, like the rejection of claim 1, relies upon Osadchy as disclosing this limitation. Ans. 8-9. Appellants repeat the arguments used against the rejection of independent claim 1. App. Br. 17-20. We find no distinction in independent claim 52 warranting a deviation from our analysis of claim 1, *supra*, and thus, we sustain the rejection of independent claim 52.

Appeal 2010-001453

Application 10/674,914

Rejection of claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Osadchy, and Burnside

Claim 10 depends from independent claim 1. The rejection of claim 10 relies upon the same finding as claim 1 that Osadchy discloses an electronic identification device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing between those elements. Ans. 9-10 (referring to Ans. 3-5). Appellants contend that claim 10 is allowable by virtue of its dependence from claim 1. App. Br. 21; Reply Br. 4. For the reasons explained in the analysis of claim 1, *supra*, we sustain the rejection of claim 10.

Rejection of claims 38-40 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Garibaldi, and Osadchy

Garibaldi discloses a magnetic medical device with changeable magnetic moments and methods of navigating such devices. Garibaldi, col. 1, ll. 9-12. Garibaldi discloses that the magnetic torque on the distal end of the catheter is directly proportional to the magnetic moment of the magnetic medical device and the applied navigating magnetic field. Garibaldi, col. 4, ll. 36-39. Garibaldi further discloses that, “for a coil, the magnetic moment is directly proportional to the product of the number of turns in the coil, the current through the coil, and the cross-sectional area of the coil wire.” Garibaldi, col. 4, ll. 39-42. Garibaldi does not disclose a relationship between the magnetic moment of the magnetic medical device and the cross-sectional area of the magnetic medical device. Garibaldi, *passim*.

Consequently, Garibaldi discloses that the cross-sectional area of the coil of wire within a flexible medical device (e.g., a catheter) is related to the

magnetic moment of a coil of such wire, but Garibaldi does not disclose a relationship between the magnetic moment of a flexible medical device and the cross-sectional area of that device. Since Garibaldi does not disclose a relationship between the magnetic moment of a flexible medical device and the cross-sectional area of that device, Garibaldi fails to demonstrate that one of ordinary skill in the art would have recognized the cross-sectional area of the device as a variable directly bearing on the magnetic field required to effect a desired torque in the device. Hence, Garibaldi does not disclose a memory device on a flexible medical device that includes information on one or more cross-sectional areas of the elongate device as called for in independent claim 38. Given this, we fail to see, and the Examiner has failed to convincingly articulate how a person of ordinary skill in the art would have been led to the subject matter of independent claim 38.

We do not sustain the rejection of independent claim 38, or its dependent claims 39 and 40.

CONCLUSIONS OF LAW

The proposed combined teachings of Stereotaxis and Osadchy would have rendered the subject matter of independent claim 1 obvious to a person having ordinary skill in the art.

The proposed combination of Stereotaxis, Osadchy, and Garibaldi would not have led a person of ordinary skill in the art to the subject matter of independent claim 38.

DECISION

We affirm the Examiner's decision to reject claims 1-6, 8, 9, 11-17, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis and Osadchy.

We affirm the Examiner's decision to reject claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Osadchy, and Burnside.

We reverse the Examiner's decision to reject claims 38-40 under 35 U.S.C. § 103(a) as being unpatentable over Stereotaxis, Garibaldi, and Osadchy.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

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